DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
HFE-35 m3139n

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

NOV 2 1999

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Naishu Wang, M.D., Ph.D., President
Alfa Scientific Designs, Inc.,
11494 Sorrento Valley Road, Suite M
San Diego, CA 92121

W/L # 04-00

Dear Dr. Wang:

During an inspection of your firm conducted between August 4- 11, 1999, an investigator from the Food and Drug Administration (FDA) determined that your firm manufactures and distributes the Lateral Flow Rapid HIV 1/2 Whole Blood Test (Regular Cassette) test kit. The test kit is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection determined that the Lateral Flow Rapid HIV 1/2 Whole Blood Test (Regular Cassette) test kit is in domestic commerce because the test kits are sold by your firm to distributors in the United States. Therefore, the Lateral Flow Rapid HIV 1/2 Whole Blood Test (Regular Cassette) test kits are adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f) of the Act and there is no approved application for premarket approval in effect pursuant to section 515(a), or an approved application for investigation device exemption under section 520(g). The inspection showed that the Lateral Flow Rapid HIV 1/2 Whole Blood Test (Regular Cassette) test kit does not meet the requirements for either of the applicable export exemptions of the Act, sections 801(e)(2) and 802. As a result, the products may not be legally exported, and are fully subject to the Act and other requirements.

With respect to exportation of the device, your firm is in violation of the Act as follows:

1. The Lateral Flow Rapid HIV 1/2 Whole Blood Test (Regular Cassette) test kit does not comply with the requirements outlined in section 802(b)(1)(A) of the Act in that you have not demonstrated that the device: (1) complies with the laws of the country to which the device has been exported and (2) has a valid marketing authorization by the appropriate authority. In addition, the device does not comply with section 801(e)(2) of the act in that you did not receive permission from the FDA to export the device.

2. The Lateral Flow Rapid HIV 1/2 Whole Blood Test (Regular Cassette) test kit is in domestic commerce contrary to section 801(e)(1)(D) of the Act, which sets forth one of the requirements for export under section 802 and section 801(e)(2) of the Act, because the test kit is sold by your firm to distributors in the United States. Unapproved products for export cannot be sold or offered for sale in domestic commerce.

3. You are in violation of section 802(g) of the Act in that you failed to comply with the requirements for simple notification to the Secretary.

This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that your facility is in compliance with the provisions of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may consider this information when awarding government contracts. Please be advised that requests for Export Certificates will not be approved until the violations related to the subject device have been corrected.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken or will take to correct or prevent these deviations. Your response should include your intentions with respect to the test kits that have been shipped in domestic commerce. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Additionally, please advise us of any action you have taken or plan take to address the previously distributed product.

Your reply should be sent to Thomas L. Sawyer, Director, Compliance Branch, and a copy to Dannie E. Rowland, Compliance Officer, at U.S. Food and Drug Administration, 19900 MacArthur Blvd., Suite 300, Irvine, California 92612-2445.

FDA has many regulatory requirements pertaining to the manufacture and marketing of medical devices. This letter addresses issues of premarket approval and export and does not necessarily address other requirements under the Federal Food, Drug, and Cosmetic Act . To obtain general information about all of FDA's regulatory requirements for manufacturers of medical devices, including information on premarket approval applications, contact:

The Division of Manufacturers Assistance, Center for Devices and Radiological Health at phone number: 1-800-638-2041, FAX: 301-443-8818, or through our Internet website at http://www.fda.gov/cdrh.

Sincerely,

James E Kozick

Acting District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
601 North 7th St. MS-357
P.O. Box 942732
Sacramento, CA 94234